UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,376	09/20/2004	Norbert Staimer	NAGACO.211A	6521

20995 7590 04/11/2006

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
JUNG, UNSU	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,376	STAIMER ET AL.	
	Examiner	Art Unit	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *14-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☒ Claim(s) *2-13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13 are pending.

Election/Restrictions

2. Applicant's election without traverse of Group I (claims 1-13) in the reply filed on November 7, 2005 is acknowledged.

Drawings

3. The drawings are objected to because the reference number "152", which is defined as an interrogation beam in the specification p14, paragraph [0065], line 7, is indicated as "incident beam" in Fig. 6 and reference numbers "140"'s are not pointing to the same element in Fig. 11. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after

the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The use of the trademark VIVAPURE® (p24, paragraph [0094], line 3) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

5. Claims 2-4, 12, and 13 are objected to because of the following informalities: a comma is need preceding the word "further" in line 1. Appropriate correction is required.

6. Claims 5-11 are objected to because of the following informalities: a comma is need preceding the word "wherein" in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The parameter "circular substrate" has been rendered indefinite by the use of the term "substantially."

9. Regarding claim 5, the phrase "such that" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-5 and 8-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (U.S. Patent No. 6,632,399, Filed May 19,1999).

Kellogg et al. anticipates instant claims by teaching a chromatographic optical bio-disc (column 6, lines 41-65 and column 8, line 24-column 9, line 27) comprising a cap portion having inlet (sample entry port) and vent ports (air ports) formed therein (column 20, lines 36-49 and Fig. 6A), a first channel layer having a first set of flow channels (capillary 402 in Fig. 6A) formed therein (column 20, lines 50-61 and Fig. 6A), a chromatographic layer having pass through ports formed therein (column 21, line 60-column 22, line 8 and column 50, lines 19-50), a second channel layer having a second set of flow channels (capillary 420 in Fig. 6A) formed therein (column 21, lines 14-29 and Fig. 6A), and a substantially circular substrate having a center and an outer edge (Fig. 13C).

With respect to claims 2-5, Kellogg et al. teaches the optical bio-disc of claim 4, wherein the chromatography membrane are place on the pass through ports such that when a sample is introduced through the inlet port, the sample moves into the first set of flow channels, through the chromatography membranes and the pass through ports, into the second set of flow channels and into the capture zone (column 21, lines 14-29, column 47, lines 39-43, and Fig. 6A).

With respect to claim 8, Kellogg et al. teaches the optical bio-disc of claim 5, wherein the chromatography membranes have binders associated therewith (affinity chromatography, column 50, lines 29-32).

With respect to claims 9 and 10, Kellogg et al. teaches the optical bio-disc of claim 8, wherein the binders are directed to glycated or non-glycated hemoglobin (column 37, lines 19-58).

With respect to claim 11, Kellogg et al. teaches the optical bio-disc of claim 1, wherein the substrate includes encoded information associated therewith, the encoded information being readable by a disc drive assembly to control rotation of the bio-disc (column 4, lines 54-60 and column 8, lines 56-66).

With respect to claim 12, Kellogg et al. teaches the optical bio-disc of claim 1, further comprising a reflective layer associated with the substrate (column 8, lines 66-67).

With respect to claim 13, Kellogg et al. teaches the optical bio-disc of claim 1, further comprising an enzyme, wherein the enzyme, when exposed to an enzyme substrate (Table II), produces a signal detectable by an incident beam of electromagnetic radiation (column 46, line 25-column 48, line 22).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (U.S. Patent No. 6,632,399, Filed May 19,1999) in view of Virtanen (U.S. Patent No. 6,030,581, Feb. 29, 2000).

Kellogg et al. teaches a chromatographic optical bio-disc as discussed above. However, Kellogg et al. fails to teach a chromatographic optical bio-disc, wherein the chromatography membranes are ion exchange membranes or membrane adsorbers.

Virtanen teaches an optical disk adapted to be read by an optical reader to conduct assays such as chromatographic assays (column 4, lines 17-53). Virtanen teaches a variety of chromatographic columns including adsorbent and ion exchange columns to be used with the optical disk (column 7, lines 54-64). The particular material is chosen for the particular application, for which it is used (column 7, lines 56-58). Examples of potential uses include separating smaller molecules from larger ones and fractionating hydrophilic and hydrophobic compounds (column 7, lines 58-61). The ion exchange column is especially useful for the separation of nucleic acids from other biomolecules (column 7, lines 61-62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the chromatographic bio-disc of Kellogg et al. with adsorbent and ion exchange membranes as taught by Virtanen in order to prepare a sample prior to affinity chromatography assay by separating smaller molecules from larger ones, fractionating hydrophilic and hydrophobic compounds, and separating nucleic acids from other biomolecules as the ion exchange membrane is especially useful for the separation of nucleic acids from other biomolecules. Furthermore, it would be obvious to one of ordinary skill to realize that performing the sample preparation step prior to affinity chromatography assays would be advantageous

because removing undesired components in the sample and further enriching the type of molecule of interest would enhance the efficiency of affinity chromatography assays.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-5, and 8-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/828,732 in view of Kellogg et al. (U.S. Patent No. 6,632,399, Filed May 19, 1999).

Copending Application teaches a chromatographic optical bio-disc comprising a cap portion having inlet and vent ports formed therein, a first channel layer having a first

set of flow channels formed therein, a second channel layer having a second set of flow channels formed therein, and a substantially circular substrate having a center and an outer edge (Fig. 13C). However, copending Application fails to teach a chromatographic optical bio-disc, further comprising a chromatographic layer having a pass through ports formed therein.

Kellogg et al. teaches a microsystem platform for use in performing biological, biochemical, and chemical analyses and syntheses that can move fluids within the structural components of a Microsystems platform (column 3, lines 50-55). Such biological assays include affinity chromatographic separation methods (column 50, lines 29-51), which would be useful for certain analytes such as the relative fraction of glycated hemoglobin in the bloodstream are important for diagnosis and monitoring of acute and chronic disease in humans (column 1, lines 41-42). It is an advantage of centrifugal rotors and microsystem platform that imprecise amount of a fluid comprising a biological sample can be applied to the rotor or platform and a precise volumetric amount of the biological sample is delivered to a fluid reservoir comprising (column 4, lines 9-26) a chromatographic optical bio-disc (column 6, lines 41-65 and column 8, line 24-column 9, line 27) comprising a cap portion having inlet (sample entry port) and vent ports (air ports) formed therein (column 20, lines 36-49 and Fig. 6A), a first channel layer having a first set of flow channels (capillary 402 in Fig. 6A) formed therein (column 20, lines 50-61 and Fig. 6A), a chromatographic layer having pass through ports formed therein (column 21, line 60-column 22, line 8 and column 50, lines 19-50), a second channel layer having a second set of flow channels (capillary 420 in Fig. 6A) formed

therein (column 21, lines 14-29 and Fig. 6A), and a substantially circular substrate having a center and an outer edge (Fig. 13C).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the chromatographic optical bio-disc of copending Application with a chromatographic layer having a pass through ports formed therein as taught by Kellogg et al. in order to perform biological assays such as affinity chromatographic separation assays, which would be useful for certain analytes such as the relative fraction of glycated hemoglobin in the bloodstream important for diagnosis and monitoring of acute and chronic disease in humans as the optical bio-disc apparatus would allow a delivery of a precise volumetric amount of the biological sample to a fluid reservoir during the affinity chromatographic separation assays.

This is a provisional obviousness-type double patenting rejection.

Conclusion

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Unsu Jung, Ph.D.
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
03/31/07